Missouri Department of Health and Senior Services'

BUREAU OF NARCOTICS & DANGEROUS DRUGS

July 2010 www.dhss.mo.gov/BNDD

Printing of Certificates Ends

When individual registrants are issued their BNDD registrations, their registration information is available on line at the bureau's website www.dhss.mo.gov/BNDD. The bureau's website is used by employers and insurers to verify current registration data and an online verification certificate can be printed from the bureau's website.

As a cost saving measure beginning July 1, 2010, the BNDD will no longer be printing and mailing certificates to individual registrants. Individual registrants, their employers and insurers may obtain a certificate of verification from the bureau's website.

Registrants that are businesses and not individuals such as pharmacies, hospitals, LTCFs, distributors, and laboratories will continue to receive a printed certificate because registrants that are not individuals are not searchable on the bureau's website.

Meth-Precursor Database Update

The BNDD has drafted rules and they are currently being filed this week. Although they will be filed as emergency rules to go into effect immediately, the enforcement date will not begin until 90 days after the rules are filed. In the meantime, the BNDD is working with the database provider, Appriss Inc., by providing them with names and addresses of all retail pharmacies and law enforcement agencies. Appriss will be sending information letters to all parties concerning the database and available training courses.

Pharmacy Theft Trends

There was a day when a tempted pharmacy employee may divert a tablet at a time by under-filling a prescription or raking an extra tablet off into their pocket.

As diverting employees became more brazen they advanced to creating false prescriptions. Some employees have simply stolen drugs from the stock bottles and then changed the inventory amounts in the pharmacy computer system.

Regulatory and law enforcement agencies have noticed a more disturbing trend during the past 8 months. Pharmacy employees are simply stealing entire stock bottles from the shelves. No actions are being taken to hide their theft. They simply stole 2 to 4 stock bottles per week. This went on for long periods of time without being noticed.

The employees were not caught until they were arrested for DWI, or found in illegal possession by the police or in one instance the theft was noticed because they stole the very last bottle that was available.

The BNDD has received theft reports and are taking actions in the following examples:

1. Western Missouri -28,174 doses
2. Eastern Missouri -14,660 doses
3. Eastern Missouri -20,859 doses
4. Southeast Missouri -49,402 doses
5. Western Missouri -20,473 doses
6. Southeast Missouri -42,889 doses
7. Central Missouri -19,778 doses

What do all of these cases have in common?

- The primary drug stolen was hydrocodone;
- Entire stock bottles were stolen several times per week;
- No efforts were made to hide the theft;
- Employees were allowed to bring purses and coats into the stock area;
- The pharmacists were never conducting any audits, reviews or inventories. There was little to no supervision. The thefts went on for months.

College Students Abusing Stimulants

Some students refer to it as "your brain on steroids." Some students are calling it "neuroenhancement." On April 25, 2010, the CBS television show *60 Minutes* ran a feature on college students abusing Adderall™ and Ritalin™.

- 2,000 students were surveyed at the University of Kentucky;
- The majority were stimulant abuse was a common practice;
- 34% admitted to taking the stimulants illegally, without a prescription;
- Only 4% of the students had prescriptions that were legal;
- The percentage of Juniors and Seniors using stimulants was pushing 60%. It increased to 80% if they were in a fraternity or sorority;

Students believed that there was a big payoff for taking the pills. The increase in dopamine makes them feel more alert, focused, interested and motivated. Students who did not abuse stimulants felt disadvantaged to those who had access to stimulants.

Students share their medications and also sell their medications for cash. Many insurers are offering a price break for the 90-day supply so there is an ability to have large quantities available on campus.

Physicians are reminded of the following information:

- ✓ At the BNDD website, www.dhss.mo.gov/BNDD, under the link to PUBLICATIONS, there is a Guide to Preventing Prescription Fraud. Please review those tips to protect your practice;
- ✓ An established and legitimate physician/patient relationship is always required. This includes a patient chart with history, complaints, dates seen, physical exams, plans and medications;
- ✓ The medications and therapies prescribed should match the diagnosis;
- ✓ Requests for early refills and claims of lost or stolen drugs should be reviewed as possible attempts at diversion. Patients running short too soon should be addressed appropriately;
- ✓ Schedule II medications are normally prescribed for up to a 30-day supply. The statute says a supply may be increased up to 90 days, if the physician documents a valid medical reason on the prescription. A valid medical reason must be documented. "Going away to college" or "great price-break on prescription" is not a valid medical reason.

ELECTRONIC PRESCRIBING REQUIREMENTS

The DEA has published their federal rules for the electronic transmission of controlled substances. The federal rules went into effect June 1, 2010 and registrants may begin to participate in electronic prescribing as soon as they have received certification their system is approved.

The BNDD does not plan on implementing any new state rules or additional requirements to participate in electronic prescribing. The BNDD will be amending its existing rules to basically say, "registrants may participate in electronic prescriptions as authorized by federal regulations." Missouri registrants may begin to participate when they have met the federal requirements.

To see the federal rules and guidelines, you may visit the DEA website at www.deadiversion.usdoj.gov and look under their link to Federal Register publications and new rules for 2010. You may also view and print the federal rules from the BNDD website www.dhss.mo.gov/BNDD. Under the link to PUBLICATIONS, the DEA Electronic Prescribing Rules are posted, along with the Economic Impact Analysis and fiscal note information for estimating the costs of participating.

The BNDD has reviewed the federal rules and attended meetings with the DEA where the rules were reviewed and discussed. A summary of the major points appears on the next page.

ELECTRONIC PRESCRIBING—MAJOR ISSUES

1. The previous forms of transmission, writing, telephoning and faxing are still permitted where applicable;
2. The option of electronic prescribing is a new voluntary option and it is not mandatory or required;
3. The new federal rules are effective June 1, 2010. Missouri registrants may begin when they have met all the federal guidelines. Missouri will not be implementing additional requirements;
4. Prescriptions may be transmitted electronically in Schedules 2,3,4, and 5;
5. There are certain requirements for practitioners, for pharmacies, and for hospitals. Practitioners will be focusing on security and manner of transmitting. Pharmacies will be focusing on security and archiving;
6. Not all providers may be ready at the same time. A doctor may be ready to transmit, but a local pharmacy may not be ready yet to receive. It will take some time for all parties to become authorized;
7. There are medical software companies such as Surescripts™; E-Scripts™; DoctorsFirst™ that may be close to having an approved system in place. These companies are called "application providers." They will have their new systems audited and reviewed by a third-party independent company. Once they have received clearance from the auditing company, these application providers will receive authorization and a certificate to begin implementing their software and hardware systems. There are similar software companies for pharmacies such as QS1™. These software providers and application providers cannot implement their systems until receiving approval.
8. Once the application provider has received a certificate and is authorized to begin, these providers may begin providing their systems to individual practitioners and pharmacies. The doctors should receive a certificate from the software provider that shows they are an approved provider. These software providers may also provide the practitioners with a certificate that shows the practitioners are authorized to electronically prescribe using their system.
9. **CAUTION:** Do not begin to transmit controlled drug prescriptions yet. At this time the DEA has not approved any systems yet. Prescriptions are not to be created and transmitted until after the audit and certification. Registrants can only use systems that meet the federal DEA requirements.
10. What starts electronic—must stay electronic: If a practitioner transmits an electronic prescription, it shall arrive at a pharmacy and then be stored and archived electronically. The practitioner cannot transmit a prescription and then have it printed to a pharmacy fax machine. A faxed prescription arrives on paper and those require a physical and manual signature before the document is faxed.
11. Participating prescribers must undergo "identity proofing" before hitting the send/transmit button each time. It has to be verified it is the proper registrant who is transmitting the prescription. There are three ways to verify identity and prescribers will be required to provide any two of them:
    A. Something you know…..…….a user ID or password;
    B. Something you are…..…….a fingerprint scan or retina eye scan;
    C. Something you have…..……...a USB device to be inserted or smartcard to swipe;
12. A prescription gets filled out with all of the information required. The prescriber must undergo two of the identify checks above before transmitting. An assistant or employee may hold an electronic device and prepare it, however only the registered practitioner with proper identity may transmit it. The completion of the two-factor identity code is considered part of the signature;
13. A digitally scanned in signature or an email sent to follow up and verify is not considered an acceptable method of identity proofing;
14. Prescriptions can only be transmitted for one patient at a time;
15. Prescriptions must be transmitted as soon as possible after identity proofing/signature;
16. If any prescription data/record is printed after transmission, the document must be labeled COPY ONLY—NOT VALID FOR DISPENSING;
17. If the transmission fails: The prescriber must be notified the transmission failed, then, the prescription may be printed out for manual signature. The prescription must document the initial prescription was electronic, name of pharmacy, date and time;
18. Controlled drug records must be maintained for two years;
19. Pharmacies have controls on who is allowed to access and retrieve data. Any changes or annotations must also be electronic. Receipt of a prescription is documented electronically;
20. Pharmacy records must be backed up daily and retained electronically.

All questions should be submitted to the DEA